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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,432	10/02/2000	James B. McCarthy	110.01130101	3387

7590 02/18/2004

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,432

Applicant(s)

MCCARTHY ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) 31-36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 29 is/are allowed.
- 6) ☒ Claim(s) 7-11, 23-28, 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the response filed 1/27/04, claims 6, 30-33, 35 have been amended. Claims 6-11, 23-36 remain pending. Claims 23-28 and 30 are now rejoined with the elected group. Claims 31-36 remain withdrawn from consideration. Claims 6-11, 23-30 are examined in this Office action.

Applicants' arguments filed 1/27/04 have been considered and found persuasive. The previously imposed rejections are withdrawn.

Claims 7-11, 23-28, 30 are now rejected. Claims 6 and 29 are characterized as allowable.

※

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9, 23, 24, 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejected claims recite that adhesion of cells to a substrate can be "modulated". The term "modulate" encompasses not only inhibition of cell adhesion, but enhancement of cell

adhesion. It is to this latter embodiment that this rejection is directed. The specification provides evidence that the claimed peptides can inhibit alpha 4 beta 1-dependent adhesion of cells to fibronectin. However, the specification provides no guidance or direction as to how the skilled artisan can increase cell adhesion to substrates. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988), the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. For the skilled artisan endeavoring to increase cell adhesion to substrates, the data in figures 1-19 actually represents a kind of failure. Clearly, enhancement of cell adhesion to substrates is not inevitable. The skilled artisan endeavoring to determine what structural features that a peptide must possess in order to achieve enhancement of cell adhesion would conclude that the structural features which give rise to such enhancement are "unpredictable". Further, the specification provides no guidance as to the structural features a peptide must exhibit in order for such enhancement of cell adhesion to be realized. The specification provides no suggestion as to what experimental procedures one should follow in order to achieve such enhancement. The specification does not even discuss prior art methods which the

skilled artisan could potentially adapt to conduct experiments that might ultimately result in such enhancement of cell adhesion. And as indicated, the specification actually provides considerable evidence that the structural features which might give rise to such enhancement of cell adhesion are unpredictable.

Thus, in view of the absence of any guidance or working examples showing enhancement of cell adhesion, the absence of any evidence that peptides can be used to enhance cell adhesion, and the demonstrated “unpredictability” of peptides to promote cell adhesion, the skilled artisan would conclude that “undue experimentation” would be required to use the claimed peptides to enhance cell adhesion to substrates. It then follows therefrom that for the skilled artisan endeavoring to “modulate” cell adhesion to substrates, “undue experimentation” would be required as well.

※

Claims 7-11, 23-28 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 7-10 recites that the peptide either inhibits or modulates adhesion. However, these claims are indefinite as to what first entity is adhering to what second entity.

- Each of claims 23-28 is drawn either to a method of inhibiting adhesion of cells to fibronectin fragments, or else encompasses such a method (i.e., “modulating”). As such, the claims are indefinite as to the manifestations of a successful inhibition.

How does one distinguish a cell/fibronectin mixture in which adhesion has been inhibited from a cell/fibronectin mixture in which adhesion has not been inhibited?

※

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 30 is rejected under 35 U.S.C. §102(b) as being anticipated by Stewart (USP 4,923,963).

Stewart discloses (col 13, line 47) the following peptide:

Arg-Pro-Pro-Gly-Phe-Ser-Pro-Phe-**Arg-Ile-Tyr**

This is a peptide “having” the sequence Arg-Ile-Tyr, and which “retains a C-terminal Ile-Tyr dipeptide sequence”. This peptide consists of 11 amino acids. The number 11, of course is not exactly the same as the number 10, but the number 11 is “about” the same as the number 10.

Thus, the peptide of Stewart meets the requirements of claim 30, given that it has “about” 10 amino acids.

✱

Claim 30 is rejected under 35 U.S.C. §102(a) as being anticipated by Kubo (WO 97/34617).

Kubo discloses (page 38) SEQ ID NO: 55, which has the following sequence:

S-T-N-E-V-T-R-I-Y

This is a nonapeptide “having” the sequence Arg-Ile-Tyr, and which “retains a C-terminal Ile-Tyr dipeptide sequence.

Thus, the claim is anticipated.

✱

Additional Art of Relevance:

- Dall (WO 97/12906) discloses (figure 1B) the following sequence:

M-I-R-I-Y-I-I-V-Y-L-F-F-I-I-I-F-I-V-L-K-S-K-R-G-N-D-N-D-N-D-N-D-N-D-N-D-S-D-H-E-F-S-C-V-N-R-P-I-N-Q-N-K-N-K-N-K-I-Y

This contains the tripeptide R-I-Y (at residues 3-5), and at the same time, bears the dipeptide Ile-Tyr at the C-terminus

- Black (WO 97/30070) discloses (page 553) SEQ ID NO: 513 which bears the following tetrapeptide at its C-terminus: Ala-Arg-Ile-Tyr

Any inquiry concerning this communication or earlier communications

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from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 4/9/04

Christopher S. F. Low
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